

REMARKS

Applicants are in receipt of the Office Action mailed October 4, 2007. Applicants note that prosecution was reopened in this application after payment of the Issue Fee. Accordingly, Applicants hereby petition the Director for a refund of the Issue Fee already paid in this matter to the Applicants' Deposit Account 01-0885.

Priority Date of the Present Patent Application

The present patent application, filed October 30, 2001, claimed priority to 60/244850, filed November 1, 2000 in the application papers. In a Notice to Comply with Requirements for Patent Applications containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures mailed March 26, 2002 the USPTO informed the Applicants that page 14 of the specification appeared to have been omitted from the specification when the application was filed.

On April 26, 2002 Applicants filed a Petition under 1.182 (Questions Not Specifically Provided For) requesting the entry of page 14 into the already-filed specification, and requesting that only this page 14 be given the filing date of the Petition (April 26, 2002). The missing page and a Supplemental Declaration accompanied the Petition.

On August 14, 2002 a Decision on Petition was mailed in which the Decision stated: "This is a decision on the petition filed

April 26, 2002 under 37 CFR 1.182 to permit entry of page 14 of the specification. The Petition is **granted.**"

However, the petition was not granted insofar as Applicants never requested or agreed to abandon the priority claim to the provisional patent application. Indeed, the priority claim to the remaining pages of the patent application (which disclose the invention claimed herein as required by 35 USC 112 without any need to refer to page 14).

Applicants therefore are herewith filing a new Rule 1.182 Petition in which it is requested that either subject matter depending upon disclosures found only on page 14 of the specification be given a priority date of April 26, 2002, or in the alternative, that page 14 be deleted from the present patent specification and the properly claimed priority of November 1, 2000 be restored.

#### **Rejection Pursuant to 35 USC §102(e)**

Claims 16, 18-22, 39 and 40 were rejected 35 USC §102(e) as allegedly anticipated by U.S. Patent No. 6,465,464. Applicants respectfully traverse this rejection for the following reasons.

An invention is anticipated only if each and every element of the claimed invention is disclosed in a single prior art reference. See, e.g., *In re Paulsen*, 30 F.3d 1475, 31 USPQ2d 1671 (Fed. Cir. 1994).

Claim 16 (the sole independent claim) has been amended to indicate that the intensity of electromagnetic radiation used in the methods of the present invention is between 150 and 900 mW/cm<sup>2</sup>. Such claim amendment is supported by the specification at, e.g., the paragraph bridging g pages 16 and 17. This newly added element of claim 16 is neither expressly found in the '464 reference, nor inherently (i.e., inevitably) found in either the description of PDT provided in such reference or in PDT treatment generally.

Additionally, claim 16 indicates that the amount of brimonidine is sufficient to protect a plurality of ocular neurons from cell death caused by a photoactive component of the PDT treatment. By contrast, the '464 patent discloses that "the laser treatment can cause photic damage to the retina" during PDT, and that the compounds disclosed therein protect the retina from "damage by the laser light" (rather than the photoactive component) used in PDT. See '464 patent, paragraph bridging column 5 and 6. It is therefore clear that the '464 reference is discussing a different method than the currently claimed method, one in which the dosage of brimonidine is correlated to damage caused by laser light rather than, as in the present claims, to damage caused by a photoactive component of the PDT treatment.

For these reasons the claims are not anticipated by the '464 patent, and Applicants respectfully ask the Examiner to withdraw this ground of rejection.

Claims 16, 18-22, 39 and 40 were also rejected pursuant to 35 USC 102(b) over U.S. Patent No. 6,194,415 and pursuant to 35 USC §102(e) and (a) over U.S. Patent No. 6248,741. Applicants

respectfully submit that the disclosures of these patents are substantially identical to that of the '464 patent, and therefore these patents do not anticipate the present invention for the reasons stated above with reference to the '464 patent. Furthermore, as stated above, Applicants believe that the present application (except page 14) is entitled to a priority date of November 1, 2000, and that all these references are solely available as prior art under 35 USC 1002(e), if at all.

Rejections Pursuant to 35 USC §103(a)

Claims 16,18-22 and 30 were rejected as allegedly obvious over the disclosure of U.S. Patent No. 6,465,464 (Wheeler), in light of US Patent Publication 2002/0040015 (Miller). Applicants respectfully traverse this rejection for the following reasons.

Both the subject matter of U.S. Patent No. 6,465,464 and the invention claimed in the present application were, at the time the invention was made, owned and subject to a duty of assignment to the same entity, Allergan, Inc. Therefore, pursuant to 35 USC 103(c) (as amended effective November 29, 1999), the patentability of the present invention is not precluded by the '464 reference, which is used as 35 USC 102(e) prior art. Accordingly, the '464 patent is not available as 35 USC §103(a) prior art against the present invention.

Furthermore, the Miller et al. publication is unavailable as prior art against any of the present claims for the reasons presented in the argument beginning on page 5 of the Amendment filed December 27, 2006, which applicants now hereby incorporate by reference in its entirety.

Claims 16-18-22 and 30 were rejected as allegedly obvious over a) U.S. Patent No. 6,194,415 in view of Miller and b) U.S. Patent No. 6248,741 in view of Miller. Applicants respectfully submit that, pursuant to the Petition filed herewith as described above, the present application (except page 14) is entitled to a priority date of November 1, 2000, and that all these references are solely available as prior art under 35 USC §102(e), if at all. Due to this, the '415 patent and the '741 patent are submitted to be disqualified as prior art. Similarly, as stated above, the US Patent Publication 2002/0040015 (Miller) is submitted to be disqualified as prior art pursuant to *In re Wertheim*.

#### Non-Statutory Obviousness-Type Double Patenting

Claims 16, 18-22, 30, 39 and 40 were rejected on the ground of obviousness type double patenting over a) U.S. Patent 6,194,415, b) U.S. Patent 6,248,741 and c) U.S. Patent 6,465,464, each in view of Wheeler et al. (Euro. J. Ophthalmology 1999) and further in view of U.S. Patent Publication No. UAS 2002/0040015 to Miller et al. Applicants respectfully traverse this rejection.

Non-statutory obviousness-type double patenting is a judicial doctrine in which the claims of the application at issue define an invention that is anticipated by or merely an obvious variation of an invention claimed in the earlier patent or application, wherein the same person or entity owns the patents or applications at issue. Further, "the focus of any double patenting analysis necessarily is on the claim in the multiple patents or patent applications involved in the analysis." MPEP §804. Thus, "when considering whether the invention defined in a claim or an

application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art." MPEP §804(II)(b)(1) citing *General Foods Corp. v. Studiengesellschaft Hohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992).

Respectfully, Applicants submit that the Examiner has not analyzed the indicated patents in accordance with the law concerning obviousness-type double patenting. First, "double patenting is altogether a matter of what is claimed", 972 F.2d at 1277, 23 USPQ2d at 1843. Moreover, while obviousness-type double patenting and §103 rejections may be analogous in the sense that an obviousness analysis is performed "the objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application." *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 68 USPQ2d 1865 (Fed. Cir. 2003).

However, the Office Action attempts to base the argument for double patenting on the disclosures of the patents, as well as of alleged prior art (scientific papers and patent publications of others). This is an erroneous analysis.

For example, on page 10 the Office Action admits that the '415 patent does not claim a method comprising the administration of brimonidine or an antiangiogenic compound, but attempts to combine a claim analysis with the disclosure of asserted prior art (Wheeler et al. publication and Miller et al.

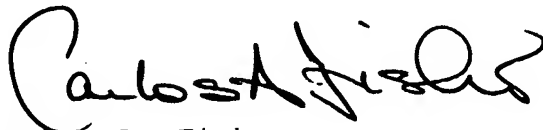
Similarly, on page 13, the analysis begins with the statement that the '464 patent "discloses and claims" a described method. As stated above, what the '464 patent discloses may not be used in a double patenting analysis except to define claim terms. As above, this analysis is impermissibly combined with the disclosure of other cited references in an attempt to support the double patenting rejection, as is the purported double patenting analysis involving the '741 patent.

In conclusion, the Office Action does not support a conclusion of obviousness-type double patenting, and Applicants therefore respectfully request that the Examiner withdraw these bases of rejection and permit the claim to proceed to issue.

#### CONCLUSION

No fee is thought due in connection with this Reply to Notice of Non-Compliant Amendment, which is being filed before the end of three month shortened statutory period for reply. However, should Applicants be in error in this regard, authorization is hereby given to charge Deposit Account No.01-0885 for any deficiency or credit any overpayment.

Respectfully submitted,



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